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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,932	02/20/2004	Michael N. Helmus	BSCI-006/00US	9710

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EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/781,932	Applicant(s) HELMUS ET AL.	
	Examiner Anand U. Desai, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 3,8-18,20-24 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,19,25-32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20050901</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, drawn to a biomaterial comprising a bioactive polymer comprised of one peptide and/or protein subunit, and one polysaccharide and/or proteoglycan subunit, and a biocompatible polymer in the reply filed on August 18, 2006 is acknowledged. Acknowledgment is made of Applicants' species election of a YIGSR peptide, Heparin as the polysaccharide and/or proteoglycan subunit, and polystyrene-isobutylene-polystyrene as the biocompatible polymer. Applicants' state claims 1, 2, 4, 5, 6, 7, 19, 22, 23, 25, 26, 27, 28, 29, 30, 31, 32, 34, 35, 36, and 37 read on the elected claims.
2. Claims 3, 8-18, 20-24, and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 18, 2006. Claim 22-24 are withdrawn, because the elected peptide sequence is YIGSR (SEQ ID NO: 16), and claims 22-24 are drawn to nonelected peptide sequence YISGR (SEQ ID NO: 19).
3. Claims 1, 2, 4-7, 19, 25-32, and 34-37 are currently pending and are under examination.

Priority

4. The priority date is the filing date of the non-provisional application. The priority date is February 20, 2004.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on September 1, 2005 has been considered by the examiner.

Specification

6. The disclosure is objected to because of the following informalities:
7. In paragraph [0012], the brief description of the drawings section is unclear. What are the lanes describing. Paragraph [0080] does not describe what was loaded in lane 2. Suggest describing the SDS gel as in paragraph [0080], and describing lane 2.
8. In paragraph [0038], the application serial number is missing.
9. In paragraph [0070], the third line has a right parenthesis after, “carbodiimide”, without a corresponding left parenthesis.
10. In paragraph [0071], the third sentence is difficult to comprehend.
11. In paragraph [0073], the first sentence appears to describes standard disaccharides or standards of disaccharides. In the fifth sentence, there are two units of measurement with the number 30. Which one is the correct unit of measurement?

Appropriate correction is required.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
13. Claims 1, 4-7, 25-32, and 34-37 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a product of nature, such as a cell. Suggest, an “artificial” biomaterial for at least claim 1.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 24, 27, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. In claim 24, it is unclear what the abbreviation, SIBS is describing. Suggest spelling out the abbreviated term in the claim.

17. In claims 27, and 34 it is unclear if the crosslinked is describing the individual crosslinking of the bioactive polymer and the biocompatible polymer, or is it describing the crosslinking of the bioactive polymer to the biocompatible polymer?

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

19. Claims 1, 4-6, 26, and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Kleinman et al. (Biochemistry 21: 6188-6193 (1982)).

Kleinman et al. describe harvested tumor tissue that comprises type IV collagen (a biocompatible polymer), laminin (a peptide), and heparan sulfate proteoglycan (see entire document, particularly Abstract, and Experimental Procedures, Preparation of Type IV Collagen section).

20. Claims 1, 2, 4, 19, 25, 26, 29, 31 rejected under 35 U.S.C. 102(b) as being anticipated by Cilento et al. (U.S. Patent 4,773,408).

Cilento et al. describe an occlusive wound dressing consisting essentially of a flexible closed cell polyurethane foam having distributed therein from about 5% to about 50% by weight of said foam of one or more water dispersible, water swellable, and/or water absorbing agents selected from the group consisting of sodium carboxymethylcellulose, calcium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, collagen, karaya, water insoluble cross-linked sodium carboxymethylcellulose, substantially water insoluble starch-acrylonitrile graft copolymer, and substantially water insoluble cross-linked dextran, a thin polymeric film or a skin laminated to one surface of said foam, and a pressure sensitive adhesive laminated to the other surface of said foam in a discontinuous pattern that covers from about 25% to about 75% of the surface of said foam (see claim 1).

21. Claims 1, 2, 4-6, 19, 25, 26, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyamoto (U.S. 2004/0136977 A1).

Miyamoto describes a crosslinked elastin, wherein the crosslinking starting material further comprises one or more components selected from among proteins such as collagen,

Art Unit: 1656

gelatin, fibronectin, fibrin, laminin, casein, keratin, sericin and thrombin, polyamino acids such as polyglutamic acid and polylysine, sugars such as polygalacturonic acid, heparin, chondroitin sulfate, hyaluronic acid, dermatan sulfate, chondroitin, dextran sulfate, sulfated cellulose, alginic acid, dextran, as well as polymethyl methacrylate, polydimethylsiloxane, polytetrafluoroethylene, silicone, polyurethane, polyethylene terephthalate, polypropylene, polyethylene, polycaprolactone, polypropylene ether, polytetramethylene glycol, polyethylene glycol, polylactic acid, polyvinyl alcohol and polymalic acid (see claim 2).

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Conclusion

22. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

October 10, 2006

A handwritten signature in black ink, appearing to be 'AD' or similar, located below the date.A handwritten signature in black ink, appearing to be 'Robert A. Wax', located above the printed name.

ROBERT A. WAX
PRIMARY EXAMINER